SCHEMA - PROTOCOL V

TITLE: A phase I/II dose-escalating trial to evaluate the safety, tolerability, and immunogenicity using a regimen of a prime and 4 boosts of a multi-clade vaccine in HIV uninfected adult participants.

DESIGN: A multicenter, double-blind, randomized, placebo controlled trial.

POPULATION: Healthy, HIV-uninfected participants in appropriate age range.

DURATION: 15 months (6 months after last vaccination).

PRIMARY OBJECTIVE(S): To evaluate the safety and tolerability of a vaccination schedule of a prime and four boosts administered at months 0, 1, 2, 6, 9.

SECONDARY OBJECTIVES: To evaluate the immunogenicity of the multi-clade vaccine.

SCHEDULE OF EVALUATIONS FOR THE FIRST TWELVE MONTHS – PROTOCOL V

Month	Screening	0	0.5	1	1.5	2	2.5	4	4.5	6	6.5	9	9.5	12
Obtain informed consent	X													
Vaccination		X		X		X				X		X		
Vaccine and reactogenicity assessments		X		X		X				X		X		
Determine HIV Status	X						X				X	X		X
Assessment of understanding	X													
Medical history and physical exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Risk reduction/pregnancy prevention counseling	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Behavioral risk assessment	X									X				X
Social impact assessment										X				X
Outside testing and belief questionnaire										X				X
Specimen Storage: plasma	X	X	X		X		X			X	X	X	X	X
Specimen Storage: serum	X	X	X		X		X			X	X	X	X	X
Specimen Storage: PBMC's	X	X	X		X		X			X	X	X	X	X
Pregnancy test	X	X		X		X				X		X		
Urinalysis	X		X				X				X		X	
Hematology	X		X		X		X				X		X	
CD4+ and CD8+ cell counts	X										X			
Chemistry panel	X		X		X		X				X		X	
RPR	X													
Hepatitis B + C Serologies	X													